General

Guideline Title

VivaScope 1500 and 3000 imaging systems for detecting skin cancer lesions.

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). VivaScope 1500 and 3000 imaging systems for detecting skin cancer lesions. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Nov 11. 54 p. (Diagnostics guidance; no. 19).

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

This guidance considers the use of VivaScope 1500 and 3000 imaging systems to help decide whether to biopsy and excise skin lesions, and to map lesion margins in people with skin cancer. The VivaScope 1500 and 3000 imaging systems are novel technologies that can image tissue at a cellular level in real time. The 4 types of skin cancer considered were melanoma, basal cell carcinoma (BCC), squamous cell carcinoma and lentigo maligna.

The VivaScope 1500 and 3000 imaging systems show promise but there is currently insufficient evidence to recommend their routine adoption in the National Health Service (NHS) for:

- Deciding whether to biopsy and excise skin lesions in people with suspected melanoma (equivocal lesions), BCC, or lentigo maligna, or
- Defining margins of skin lesions in people with lentigo maligna and BCC.

Further research on using the VivaScope 1500 and 3000 imaging systems is recommended in the following areas:

- The impact on clinical workflows for melanoma and BCC assessment in secondary care settings
- The proportion of people with melanoma referred into secondary care under the 2-week wait rule, and the outcomes achieved
- The number of confirmatory diagnostic biopsies needed for people with a clinical diagnosis of BCC, before definitive treatment is started
- The comparative clinical effectiveness of using these imaging systems to define margins of lentigo maligna and BCC
- Epidemiological research on lentigo maligna diagnosed in England

The VivaScope 1500 and 3000 imaging systems are not recommended for:

- Helping decide whether to biopsy and excise skin lesions in people with suspected invasive squamous cell carcinoma, or
- Defining margins of skin lesions in people with melanoma or invasive squamous cell carcinoma

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Skin cancer, including melanoma, basal cell carcinoma (BCC), squamous cell carcinoma, and lentigo maligna

Guideline Category

Diagnosis

Technology Assessment

Clinical Specialty

Dermatology

Oncology

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To assess the clinical effectiveness and cost-effectiveness of the VivaScope 1500 and 3000 imaging systems to:

- Help decide whether to biopsy and excise skin lesions in people with suspected skin cancer
- Define the margins of skin lesions for excision in people with skin cancer

Target Population

Individuals with suspected skin cancer lesions

Interventions and Practices Considered

Use of VivaScope 1500 and 3000 imaging systems for assessment of skin lesions

Major Outcomes Considered

- Clinical effectiveness
  - Diagnostic test accuracy, reported as sensitivity, specificity, positive predictive value and negative predictive value
  - Time to test failure (e.g., imaging failure rate)
  - Number of biopsies performed and repeat biopsies
  - Morbidity associated with excision such as pain and swelling
  - Extent of scarring and associated psychological impact
  - Lesion recurrence rates
  - Adverse events from biopsy or false test results
  - Adverse events from surgery including infections
  - Health-related quality of life
  - Misdiagnosis/misclassification of lesions
  - Change in management of lesions
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this diagnostic guidance and prepare a Diagnostics Assessment Report (DAR). The DAR for this assessment was prepared by BMJ Technology Assessment Group (BMJ-TAG) (see the "Availability of Companion Documents" field).

Assessment of Clinical Effectiveness

Methods for Reviewing Clinical Effectiveness

Inclusion and Exclusion Criteria

Inclusion and exclusion criteria in terms of population, interventions and comparators, reference standard test and outcome measures are described in Section 2 of the DAR.

Study Design

The following types of studies were eligible for inclusion:

- Randomised controlled trials or observational studies, where participants are assigned to dermoscopy plus VivaScope or VivaScope alone for diagnosis or skin lesion delineation, and where outcomes are compared at follow-up
- Test accuracy studies assessing the test accuracy of dermoscopy plus VivaScope or VivaScope alone with histology of biopsy as the reference standard

The following study/publication types were excluded:

- Pre-clinical and animal studies

- Reviews, editorials, and opinion pieces
- Case reports

Search Strategy

The searches combined terms for the condition and terms for the technology being assessed. For the technology the assessment group used both generic terms (e.g., reflectance confocal microscope) and terms for the specific product (e.g., VivaScope). The search strategy was refined by scanning key papers identified during the review, through discussion with the review team, clinical experts and information specialists.

Electronic sources included: MEDLINE, EMBASE, and the Cochrane Library (including the Cochrane Database of Systematic Reviews [CDSR], the Database of Abstracts of Reviews of Effects [DARE], the Health Technology Assessment [HTA] Database, and CENTRAL).

Electronic databases were searched from database inception on 14th October 2014 and results uploaded into Endnote Version 7.2 and de-duplicated. Full details of the terms used in the searches are presented in Appendix 9.1 of the DAR. The searches were updated on 11th February 2015.

Two reviewers independently screened all titles and abstracts according to the inclusion criteria. Full paper manuscripts of any titles/abstracts of potential relevance were obtained and assessed independently by two reviewers. Authors of papers for which insufficient details were available to allow data extraction and/or critical appraisal of study quality were contacted. Discrepancies between the two reviewers were resolved by consensus, with involvement of a third reviewer when necessary.

Potentially important ongoing and unpublished UK-based studies were also searched using: clinicaltrials.gov, controlled-trials.com, clinicaltrialsregister.eu. Reference lists of included papers were assessed for additional relevant studies, and clinical experts were also contacted for additional information on published and unpublished studies.

Relevant reviews and guidelines were identified through searching additional resources, including Clinical Evidence, NICE Web site, National Institute for Health Research (NIHR) Health Technology Assessment Programme, National Health Service (NHS) Evidence – National Library of Guidelines, Scottish Intercollegiate Guidelines Network (SIGN) Guidelines, and Guidelines International Network (GIN) Web site.

In addition, abstracts from the following key conference proceedings were searched for relevant studies from 2012:

- Annual meeting of the British Association of Dermatologists (BAD)
- Annual meeting of the British Society of Dermapathology (BSD)
- Congress of European Association of Dermato-Oncology (EADO)
- Annual meeting of the American Academy of Dermatology (AAD)
- Annual meeting of the American Society of Dermapathology (ASDP)

No limits relating to language of publication were applied to the searches.

Refer to Section 4.2 and Figure 1 of the DAR for results of the assessment of clinical effectiveness.

Assessment of Cost-effectiveness

Systematic Literature Review of Existing Economic Evidence

Methods

A systematic review of the literature was undertaken in October 2014 in order to identify published economic evaluations that assessed the cost effectiveness of VivaScope 1500 and 3000 in the diagnosis of skin lesions suspected for skin cancer and in the margin delineation of malignant skin lesions, including lentigo maligna, prior to surgical treatment. In addition, two further systematic reviews were conducted, in December 2014 and October 2014 respectively, aiming to identify:

- Studies reporting resource use and cost data associated with the care pathways of skin cancer, including the initial assessment and diagnosis of skin lesions suspected for malignancy, that could be utilised in primary economic modelling
- Studies providing utility (preference-based) data on the health-related quality of life (HRQoL) of people with suspected or confirmed skin cancer, that could be used for the estimation of quality-adjusted life years (QALYs) in the economic models developed as part of this report

The following databases were searched:

- MEDLINE (Ovid)
- EMBASE (Ovid)

- HTA database (HTA)
- NHS Economic Evaluations Database (NHS EED)

Further to the database searches, experts in the field were contacted with a request for details of relevant published and unpublished studies of which they may have knowledge; reference lists of key identified studies were also reviewed for any potentially relevant studies. Finally, the NICE Web site was searched for any recently published guidance relating to skin cancer that had not been already identified via the database searches.

The search strategy for existing economic evaluations combined terms capturing the interventions (reflectance confocal microscopy [RCM], i.e., VivaScope) and comparators of interest (dermoscopy, surgical excision and biopsy), the target condition (types of skin cancer) and, for searches undertaken in MEDLINE and EMBASE, terms to capture economic evaluations. The search strategies for resource use and cost data as well as for utility data were not restricted by intervention, and used terms capturing the target condition; in searches undertaken in MEDLINE and EMBASE, these terms were combined with cost of illness terms (resource use and cost data searches) and HRQoL terms (searches for utility data).

No restrictions on language or setting were applied to any of the searches. The search for resource use and cost data was limited to the UK/NHS setting, as the aim of this search was to identify data directly relevant to the NHS context that could inform the economic model; however, no country restrictions were applied to searches for existing economic evaluations or studies reporting utility data relating to skin cancer. Searches for HRQoL data were restricted by date, starting from 1997, due to the high volume of search hits if this restriction was not imposed; the year 1997 was selected as this was the year the utility index for the European Quality of Life five-dimension questionnaire (EQ-5D) was published. Limits were applied to remove animal studies and case studies. Conference abstracts were considered for inclusion from 1st January 2013, as high-quality studies reported in abstract form before 2013 were expected to have been published in a peer-reviewed journal. Full details of the search strategies are presented in Appendix 9.6 of the DAR.

The titles and abstracts of papers identified through the searches were independently assessed for inclusion by two health economists using pre-defined eligibility criteria. Due to the high volume of studies retrieved by the HRQoL search, one health economist reviewed all identified citations and a second health economist reviewed a random sample of 1,000 citations, to confirm that the same studies were included for second pass.

Inclusion and Exclusion Criteria

Inclusion Criteria – Existing Economic Evaluations

- Intervention or comparators according to the scope of the assessment
- Study population according to the scope of the assessment
- Full economic evaluations (cost-utility, cost-effectiveness, cost-benefit or cost-consequence analyses) that assess both costs and outcomes associated with the interventions of interest
- Economic evaluations that utilise clinical effectiveness data from randomised or non-randomised clinical trials, prospective cohort studies or systematic reviews and meta-analyses of clinical studies; economic analyses that utilise clinical data from studies with a mirror-image or other retrospective design will not be considered.

Inclusion Criteria – Resource Use and Costing Studies

- Study population according to the scope of the assessment
- UK resource use or costing studies
- Any setting (to be as inclusive as possible)

Inclusion Criteria – Studies Reporting Utility Data Relating to Skin Cancer

- Studies reporting utility data elicited using a generic or a condition-specific preference-based measure, vignettes or self-report and a validated, choice-based technique for valuation (i.e. time trade-off or standard gamble)
- Utility data referring to specific health states associated with skin cancer through the care pathway

Exclusion Criteria – All

- Abstracts with insufficient methodological details
- Conference papers pre January 2013

Refer to Section 5.1.2 and Figures 3 to 5 in the DAR for results of the economic literature searches.

Number of Source Documents

Assessment of Clinical Effectiveness

Sixteen articles met the inclusion criteria.

- Lesion diagnosis - 13 studies
- Lesion margin delineation - 3 studies

Refer to Figure 1 in the Diagnostics Assessment Report (see the "Availability of Companion Documents" field) for a flow diagram detailing the literature search results.

Assessment of Cost-effectiveness

Existing economic evidence:

- Economic evaluations - 1 study
- Resource use and costing - 3 studies
- Utility data - 6 studies

Refer to Figures 3 to 5 in the Diagnostics Assessment Report (see the "Availability of Companion Documents" field) for a flow diagram detailing the literature search results.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this diagnostic guidance and prepare a Diagnostics Assessment Report (DAR). The DAR for this assessment was prepared by BMJ Technology Assessment Group (BMJ-TAG) (see the "Availability of Companion Documents" field).

Assessment of Clinical Effectiveness

Systematic Review Methods

Inclusion Screening and Data Extraction

Data were extracted using a standardised data extraction form by one reviewer, and validated by a second reviewer after the pilot of 6 studies that was done in duplicate. Information extracted included details of the study's design and methodology, intervention and comparator tests, reference standard, baseline characteristics of participants, and outcome measures, including clinical outcome efficacy and any adverse events. Discrepancies between the two data extractors were resolved by discussion, with involvement of a third reviewer if necessary or contact with study authors for clarification.

Quality Assessment

The quality of included studies was assessed by two reviewers and the two extractions were validated. Any disagreements were resolved by consensus and if necessary a third reviewer was consulted. The quality of diagnostic studies was assessed using the quality assessment of diagnostic accuracy studies (QUADAS-2) tool, according to recommendations by the Cochrane Handbook for Diagnostic Test Accuracy Reviews. Where clinical effectiveness studies were identified that met the eligibility criteria the assessment group assessed their quality according to the study design; randomised controlled trials according to recommendations by the Centre for Reviews and Dissemination (CRD) and the Cochrane Handbook for Systematic Reviews of Interventions and recorded using the Cochrane Risk of Bias Tool. When suitable for inclusion, cohort studies were assessed using the Newcastle–Ottawa Scale.

Methods of Analysis/Synthesis

Details of results on test accuracy, clinical effectiveness and quality assessment for each included study was presented in structured tables and as a narrative summary.

For test accuracy data, results of sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) are presented in the DAR. Where these were not reported, absolute numbers of true positive, false negative, false positive and true negative test results were used to calculate sensitivity and specificity values.

Where results could be combined, the assessment group intended to use absolute numbers of effect or aggregate data (means) with standard deviations in standard frequentist meta-analyses to produce forest plots of pooled data. Heterogeneity was to be assessed by doing a sensitivity analysis regardless of the I^2 statistic.

The assessment group also planned to analyse accuracy data using patient-level data and not lesion-level data because of the difficulty in estimating within-study variance. Estimates of sensitivity and specificity and their respective confidence intervals were to be plotted in forest plots to explore heterogeneity in the first instance. A random effects meta-analysis was planned to fit the bivariate summary receiver operating characteristics (SROC) curve model with the with-in study variance fitted as binomial.

See Section 4 of the DAR for more information on clinical effectiveness analysis.

Assessment of Cost-effectiveness

Economic Models Developed – Decision Problems Addressed

According to the study populations that were identified as relevant for the economic evaluation of VivaScope (see Section 5.2.1.2 of the DAR), three separate 'part' economic models were developed:

- Use of VivaScope in the diagnosis of equivocal lesions suspected for melanoma. This model assessed the cost effectiveness of VivaScope 1500 and 3000, as one integrated system, assuming that both devices will be available for the diagnosis of equivocal lesions but each will be used as appropriate according to the location of the equivocal lesion to be examined.
- Use of VivaScope in the diagnosis of suspected basal cell carcinoma (BCC) lesions following a positive or equivocal finding in dermoscopy. As with the previous model, this model assessed the cost effectiveness of VivaScope 1500 and 3000, as one integrated system, assuming that both devices will be available for the diagnosis of suspected BCC lesions but each will be used as appropriate according to the location of the skin lesion to be examined.
- Use of VivaScope for the margin delineation of lentigo maligna prior to surgical therapy. This model assessed the cost effectiveness of VivaScope 3000 as a stand-alone device, since only this device is appropriate for margin delineation.

Using the results of the above 3 'part' models, 5 economic analyses were undertaken, examining the cost effectiveness of VivaScope in:

a. The diagnostic assessment of equivocal lesions suspected for melanoma (integrated use of VivaScope 1500 & 3000)
b. The diagnostic assessment of lesions suspected for BCC following a positive or equivocal result in dermoscopy (integrated use of VivaScope 1500 & 3000)
c. The diagnostic assessment of skin lesions suspected for skin cancer, either melanoma (following an equivocal finding in dermoscopy) or BCC (following a positive or equivocal finding in dermoscopy) – this analysis combined the results of the two respective 'part' models
d. The margin delineation of lentigo maligna prior to surgical treatment (use of VivaScope 3000 as a stand-alone device)
e. The diagnostic assessment of skin lesions suspected for either melanoma or BCC, and the margin delineation of lentigo malignas (integrated use of VivaScope 1500 & 3000) – this analysis combined the results of all three 'part' models

The final economic analysis synthesised all cost and effectiveness data from each of the 'part' economic models to obtain an estimate of the overall cost effectiveness of the VivaScope imaging system used for all indicated purposes assessed in economic modelling in a skin cancer multidisciplinary team (MDT) service.

The analyses that combined results of 'part' models used weighed total costs and benefits according to the expected relative volume of each type of lesion diagnosed and/or mapped with VivaScope in one dermatology MDT service.

See Section 5 and Appendix 9.7 of the DAR for additional information on cost-effectiveness analysis.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Developing Recommendations

After reviewing the evidence the Diagnostic Advisory Committee (DAC) agrees draft recommendations on the use of the technology in the National Health Service (NHS) in England. When formulating these recommendations, the Committee has discretion to consider those factors it believes are most appropriate to the evaluation. In doing so, the Committee has regard to any relevant provisions of the National Institute for Health and Care Excellence's (NICE's) Directions, set out by the Secretary of State for Health, and legislation on human rights, discrimination and equality. In undertaking evaluations of healthcare technologies, NICE takes into account the broad balance of clinical benefits and costs, the degree of clinical need of patients under consideration, any guidance issued to the NHS by the Secretary of State that is specifically drawn to the attention of NICE by the Secretary of State, and any guidance issued by the Secretary of State, and the potential for long-term benefits to the NHS of innovation.

The Committee takes into account advice from NICE on the approach it should take to making scientific and social value judgements. Advice on social value judgements is informed in part by the work of NICE's Citizens Council.

The Committee takes into account how its judgements have a bearing on distributive justice or legal requirements in relation to human rights, discrimination and equality. Such characteristics include, but are not confined to: race, gender, disability, religion or belief, sexual orientation, gender reassignment and pregnancy or maternity.

The Committee considers the application of other Board-approved NICE methods policies, such as the supplementary guidance on discounting and the end-of-life criteria, if they are relevant to the evaluation.

Because the Programme often evaluates new technologies that have a thin evidence base, in formulating its recommendations the Committee balances the quality and quantity of evidence with the expected value of the technology to the NHS and the public.

The credibility of the guidance produced by NICE depends on the transparency of the DAC's decision-making process. It is crucial that the DAC's decisions are explained clearly, and that the contributions of registered stakeholders and the views of members of the public are considered. The reasoning behind the Committee's recommendations is explained, with reference to the factors that have been taken into account.

The language and style used in the documents produced by the Committee are governed by the following principles:

- Clarity is essential in explaining how the DAC has come to its conclusions.
- The text of the documents does not need to reiterate all the factual information that can be found in the information published alongside the guidance. This needs careful judgement so that enough information and justification is given in the recommendations to enable the reader to understand what evidence the DAC considered and, if appropriate, who provided that evidence.

The Committee may take into account factors that may provide benefits to the NHS or the population, such as patient convenience. It may also consider costs and other positive or negative impacts on the NHS that may not be captured in the reference-case cost analysis, such as improved processes.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Base-Case Results

For the purposes of decision-making, the incremental cost-effectiveness ratios (ICERs) per quality-adjusted life year (QALY) gained or lost were considered.

Melanoma

The cost-effectiveness of VivaScope in the diagnostic assessment of suspected melanomas with an equivocal finding in dermoscopy was affected by the diagnostic accuracy data used in the model, when VivaScope was assumed to be exclusively used for this purpose. Using the more 'optimistic' diagnostic data from Alarcon et al. (2014) resulted in a probabilistic ICER of £9362 per QALY gained. The 'less favourable' diagnostic data from Pellacani et al. (2014) resulted in an ICER of £25,453 per QALY gained. When using VivaScope was expanded to include other indications assessed in the economic analysis, VivaScope became the dominant strategy, that is, it was more effective and less costly than routine management of equivocal lesions suspected as melanoma.

Basal Cell Carcinoma (BCC)

VivaScope was the dominant strategy, that is, it was more effective and less costly, when used for assessing suspected BCCs, regardless of whether it was used exclusively for assessing BCCs or all indications (suspected melanomas and lentigo malignas).

Pre-surgical Margin Delineation Economic Model

Regarding margin delineation of lentigo malignas, mapping with VivaScope was cost effective, even if it was used exclusively for this purpose, as indicated by an ICER of £11,651 per QALY gained. When use of VivaScope was expanded to other indications covered in this economic analysis, VivaScope became the dominant option, that is, it was more effective and less costly.

Considerations

Diagnosis

The Committee considered the cost-effectiveness of VivaScope in diagnosing melanoma and BCC in people with equivocal skin lesions. The Committee discussed the evidence and noted that there is uncertainty in the specificity of the VivaScope systems in diagnosing melanoma and in the accuracy of diagnosing BCC. It also noted the uncertainty in the number of biopsies that could be avoided and in the utility values used in the model. Overall, the Committee concluded that although the VivaScope systems show promise, there is too much uncertainty in the evidence for it to be confident that using the VivaScope systems represents a cost-effective use of NHS resources.

Margin Delineation

The Committee considered the clinical evidence for using the VivaScope systems to delineate margins of lentigo maligna and noted that only 1 study had been identified and it had small patient numbers. It heard from clinical experts that lower recurrence rates could be inferred from the study but noted that the study was not comparative and had short (6 months) follow-up, which limits the robustness of the findings. The Committee concluded that the VivaScope systems showed promise but further research was needed to determine their clinical effectiveness in defining margins of lentigo maligna.

The Committee discussed the cost-effectiveness of using the VivaScope systems to map margins of lentigo maligna. The Committee noted that the ICERs suggest that using the VivaScope systems is cost effective. However, it also considered the evidence informing the model and noted that there is substantial uncertainty in the diagnostic accuracy of the VivaScope systems and in the impact that their use has on lesion recurrence rates. The Committee concluded therefore, that there is too much uncertainty in the clinical evidence to determine if using the VivaScope systems is a cost-effective use of NHS resources.

See Sections 5 and 6 in the original guideline document for additional information on cost-effectiveness.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

The National Institute for Health and Care Excellence (NICE) sends the Diagnostics Assessment Report (DAR), with any confidential material

removed, to registered stakeholders for comment. Stakeholders have 10 working days to return comments. Models supporting the DAR are made available to registered stakeholders on request during this period.

NICE presents anonymised registered stakeholder comments on the DAR, along with any responses from NICE or the External Assessment Group (EAG), to the Committee and later publishes these comments on its Web site.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Diagnostics Advisory Committee considered a systematic review and cost-effectiveness analysis prepared by an External Assessment Group.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Accurate diagnosis of potentially malignant skin lesions and delineation of tumour margins for excision

Potential Harms

Adverse events arising from false-positive or false-negative test results (e.g., unnecessary treatment for skin lesions, diagnostic biopsy that causes distress/anxiety with a false-positive result; missed melanoma resulting in metastatic disease with a false-negative result)

Qualifying Statements

Qualifying Statements

- This guidance represents the view of the National Institute for Health and Care Excellence (NICE), which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

The National Institute for Health and Care Excellence (NICE) will support this guidance through a range of activities to promote the recommendation for further research. The research proposed will be considered by the NICE Medical Technologies Evaluation Programme research facilitation team for the development of specific research study protocols as appropriate. NICE will also incorporate the research recommendations (see Section 7 of the original guideline document) into its guidance research recommendations database (available on the NICE Web site) and highlight these recommendations to public research bodies.

Implementation Tools

Mobile Device Resources

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). VivaScope 1500 and 3000 imaging systems for detecting skin cancer lesions. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Nov 11. 54 p. (Diagnostics guidance; no. 19).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2015 Nov 11

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Diagnostics Advisory Committee

Composition of Group That Authored the Guideline

Standing Committee Members: Professor Adrian Newland (*Chair, Diagnostics Advisory Committee*); Dr Mark Kroese (*Vice Chair, Diagnostics Advisory Committee*), Consultant in Public Health Medicine, PHG Foundation, Cambridge and UK Genetic Testing Network; Professor Ron Akehurst, Professor in Health Economics, School of Health and Related Research (ScHARR), University of Sheffield; Dr Phil Chambers, Research Fellow, Leeds Institute of Cancer & Pathology, University of Leeds; Dr Sue Crawford, GP Principal, Chillington Health Centre; Professor Erika Denton, National Clinical Director for Diagnostics, NHS England, Honorary Professor of Radiology, University of East Anglia and Norfolk and Norwich University Hospital; Mr David Evans, Lay member; Dr Simon Fleming, Consultant in Clinical Biochemistry and Metabolic Medicine, Royal Cornwall Hospital; Mr John Hitchman, Lay member; Professor Chris Hyde, Professor of Public Health and Clinical Epidemiology, Peninsula Technology Assessment Group (PenTAG); Mr Matthew Lowry, Director of Finance and Infrastructure, Doncaster and Bassetlaw Hospitals NHS Foundation Trust; Dr Michael Messenger, Deputy Director and Scientific Manager, NIHR Diagnostic Evidence Co-operative, Leeds; Dr Peter Naylor, GP, Chair Wirral Health Commissioning Consortia; Dr Dermot Neely, Consultant in Clinical Biochemistry and Metabolic Medicine, Newcastle upon Tyne NHS Trust; Ms Gail Norbury, Consultant Clinical Scientist, Guy's Hospital; Dr Simon Richards, Vice President Regulatory Affairs, EME (Europe and Middle East), Alere Inc.; Dr Deirdre Ryan, Consultant Cellular Pathologist, Royal London Hospital; Professor Mark Sculpher, Professor of Health Economics, Centre for Health Economics, University of York; Dr Steve Thomas, Consultant Vascular and Cardiac Radiologist, Sheffield Teaching Hospitals Foundation Trust; Mr Paul Weinberger, Chief Executive Officer, DiaSolve Ltd, London; Professor Anthony Wierzbicki, Consultant in Metabolic Medicine and Chemical Pathology, St Thomas' Hospital

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Financial Disclosures/Conflicts of Interest

Committee members are required to submit a declaration of interests on appointment, in every year of their tenure, and at each Committee meeting, in line with the National Institute for Health and Care Excellence's (NICE's) code of practice for declaring and dealing with conflicts of interest.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download in ePub or eBook formats from the NICE Web site .

Availability of Companion Documents

The following are available:

- Edwards SJ, Mavranezouli I, Osei-Assibey G, Marceniuk G, Wakefield V, Karner C. VivaScope 1500 and 3000 systems for detecting and monitoring skin lesions: a systematic review and economic evaluation. Diagnostics assessment report. London (UK): BMJ Technology Assessment Group (BMJ-TAG); 2015. 295 p. Available from the National Institute for Health and Care Excellence (NICE) Web site

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- Diagnostics Assessment Programme manual. London (UK): National Institute for Health and Care Excellence; 2011 Dec. 130 p. Available from the NICE Web site .

Patient Resources

The following is available:

- VivaScope 1500 and 3000 imaging systems for detecting skin cancer lesions. Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Nov. (Diagnostics guidance; no. 19). Available from the National Institute for Health and Care Excellence (NICE) Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on January 5, 2016.

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